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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,847	10/26/2001	Charles E. Hart	00-100	9351
7590 11/26/2003			EXAMINER	
ZymoGenetics, Inc. 1201 Eastlake Avenue East Seattle, WA 98102			ANDRES, JANET L	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 11/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/039,847

Applicant(s)

HART ET AL.

Examiner

Janet L. Andres

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9/03.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

RESPONSE TO AMENDMENT

1. Applicant's amendment filed 8 September 2003 is acknowledged. Claims 13-19 are pending and under examination in this office action. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

2. The objection to the specification as referring to trademarks without capitalization is withdrawn in response to Applicant's amendment.

3. The objection to claim 20 is withdrawn in response to Applicant's cancellation of this claim.

4. The rejection of claims 13-20 under 35 U.S.C. 102(e) as anticipated by the 6495668 and 6468543 patents is withdrawn in response to Applicant's amendment. The claims are newly rejected under 35 U.S.C. 103, below.

5. The rejection of 13-20 under the judicially-created doctrine of obviousness-type double patenting is withdrawn in response to Applicant's amendment. While the effects of administration are not altered by the intended use, Applicant's amendment limits the population to be treated to a distinct group.

New Grounds of Rejection

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Art Unit: 1646

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. Claims 13-19 are newly rejected under 35 U.S.C. 103(a) as being obvious over the '668 and '543 patents in view of Lindberg et al. (Seminars in Nephrology vol. 19 (2), 1999, pp. 115-122).

The applied patents have common assignee and inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the

Art Unit: 1646

same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The '543 and '668 patents teach zveg4 as promoting bone growth (column 59 of the '668 patent and column 22 of the '543 patent). Each patent further teaches that it causes proliferation of cells in the kidney (columns 58 and 59 of the '668 patent and columns 21 and 22 of the '543 patent); however, neither patent teaches that kidney tubule epithelial cells proliferate in response to zveg4, speculating rather that endothelial cells proliferate. In addition, neither patent contemplates administration of zveg4 to patients in need of proliferation of kidney tubule epithelial cells or contemplates treatment of any sort of kidney disease. Lindberg et al. teaches renal disease and teaches that patients with such disease suffer from bone loss and a high incidence of fracture (p. 115, columns 1 and 2, p. 116, figure 1). It would have been obvious to one of ordinary skill in the art to combine the teachings of the '543 and '668 patents with those of Lindberg et al. to administer zveg4 to patients in need of kidney tubule epithelial cell proliferation. One of ordinary skill would have been motivated to do so because Lindberg et al. teaches that such patients are at risk of bone loss and would benefit from the bone-promoting activities of zveg4, and because additional benefits could be expected based on the findings of the two patents that kidney weight was increased by zveg4, regardless of the mechanism of this benefit.

With respect to the rejection under 102(e), of record in the previous office action, Applicant argues that neither patent suggest proliferation or survival of kidney epithelial cells. Applicant argues that no link was provided between need for enhanced proliferation or survival of kidney epithelial cells and bone growth. Applicant additionally argues each patent suggests

that antagonists would be useful to treat proliferative glomerulopathy. Applicant concludes that there is no motivation in either patent to administer zveg4 to patients in need of enhanced proliferation or survival of kidney epithelial cells.

As indicated above, Applicant's arguments are found persuasive with respect to the rejections under 102(e). However, as shown above, a nexus between the need for enhanced kidney function and the need for bone growth does exist, because patients with end-stage renal disease suffer bone loss. Thus, based only on the disclosed ability of zveg4 to affect bone growth, it would be obvious to administer it to patients with renal disease. Further, as stated above and in the previous office action, regardless of the mechanism, increased kidney weight was observed with zveg4, thus providing additional motivation for its administration. That the patents suggest that antagonists may be used to treat proliferative disease does not serve to teach away from this use. If antagonists are useful to prevent proliferative disease, zveg4 itself would presumably be useful to treat diseases involving loss of cell function, such as renal failure. Thus the claims are newly rejected under 35 U.S.C. 103(a) as unpatentable over the two patents in view of Lindberg et al.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Art Unit: 1646

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
November 24, 2003

A handwritten signature in black ink, appearing to read "Janet Andres", is written over a circular stamp. The stamp contains the text "PATENT AND TRADEMARK OFFICE" around the perimeter and "WASHINGTON, D.C." in the center.